

REMARKS

In response to the Office Action dated April 21, 2006, Applicant respectfully requests reconsideration in view of the following remarks. Applicant has not amended or added any claims. Claims 18-34 have been withdrawn pursuant to a Requirement for Restriction and claims 1-17 are pending.

The specification and FIGS. 9, 10, 13, 14, 16, 23, and 24 have been amended to correct inadvertent typographical errors.

Restriction Under 35 U.S.C. § 121

In the Office Action, the Examiner restricted claims 1-34 under 35 U.S.C. § 121 as follows:

- Group I. Claims 1-17, drawn to a medical device programmer, and
- Group II. Claims 18-34, drawn to a method of manufacturing the programmer.

During a telephonic conversation with the Examiner on March 22, 2006, Applicant provisionally elected Group I without traverse. Applicant affirms this election without traverse.

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, claims 1-6, 8-11 and 13-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haller et al. (US 6,804,558) in view of Lin et al. ("A Wireless PDA-Based Physiological Monitoring System for Patient Transport," *IEEE Transactions on Information Technology in Biomedicine*, pp. 439-447 (August 29, 2003)). Claim 7 was rejected under 35 U.S.C. 103(a) as being unpatentable over Haller et al. (US 6,804,558) and Lin et al. in view of Duncan et al. (US Publication 2003/0139782). Claim 12 was also rejected under 35 U.S.C. 103(a) as being unpatentable over Haller et al. (US 6,804,558) and Lin et al. in view of Stroebe et al. (US 5,754,527).

Applicant respectfully traverses the rejection of claims 1-17 under 35 U.S.C. 103(a). First, Applicant points out that the Lin et al. reference is not prior art under 35 U.S.C. 102. In the Notice of References Cited mailed with the Office Action on April 21, 2006, the Lin et al. publication date is cited as August 29, 2003. However, August 29, 2003 is the date the manuscript was first received by IEEE, not the publication date, i.e., the date that the content of

the Lin et al. paper would have been available to the public. (See Lin et al., *IEEE Transactions on Information Technology in Biomedicine*, page 439). A magazine is effective as a printed publication as of the date it reaches the addressee. See MPEP 706.02(a) and *Protein Foundation Inc. v. Brenner*, 260 F. Supp. 519, 151 USPQ 561 (D.D.C. 1966). The Lin et al. reference was published in a December 2004 issue of *IEEE Transactions on Information Technology in Biomedicine*. Therefore, the publication date of the Lin et al. reference is around December 2004, which is after the effective filing date of the present application. The copyright notice for the Lin et al. reference includes 2004 as the year of the copyright, which further evidences the fact that the Lin et al. reference was not published until 2004. For at least this reason, the rejections under section 103 must be withdrawn, at least to the extent they rely on the Lin et al. reference.

Second, Applicant traverses the rejections because the applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention, as discussed in detail below. In light of its failure to qualify as prior art, Applicant reserves further comment concerning the Lin et al. reference, but neither admits nor acquiesces in the propriety of the Examiner's application of the Lin et al. reference to the claimed invention.

Independent Claim 1

Claim 1 is directed toward a medical device programmer comprising "a first housing member, a second housing member, and a plate member attached to the second housing member, wherein the plate member includes a transparent area that exposes a display for viewing, and the plate member is printed with information to identify a programmer type associated with the medical device programmer."

The Haller et al., Duncan et al., and Stroebel et al. references, alone or in combination, fail to teach or suggest the invention of Applicant's independent claim 1 or claims 2-17, which depend from claim 1. For example, the references of record do not disclose a programmer including a "plate member . . . that exposes a display for viewing, and . . . is printed with information to identify a programmer type associated with the medical device programmer," as recited by Applicant's claim 1.

The Office Action interpreted col. 31, lines 8-13, of Haller et al. as teaching a plate member attached to a second housing member. (See Office Action, page 3, item 8). However, at col. 31, lines 8-13, Haller et al. only states that a mobile telephone or a PDA/mobile telephone may have a removable faceplate. This statement in Haller et al. does not render Applicant's independent claim 1 obvious, even in combination with Duncan et al. and Stroebel et al. Haller et al. does not indicate where the faceplate is attached, whether the face plate exposes a display for viewing, or whether the faceplate is printed with identifying information. Applicant's claim 1 clearly recites a plate member "attached to the second housing," including "a transparent area that exposes a display for viewing," and "printed with information to identify a programmer type," none of which is suggested by Haller et al.

The Office Action asserted that FIG. 6A of Haller et al. illustrates a plate member covering at least a portion of a display and exposing the display for viewing. (Office Action, page 3, item 8). However, FIG. 6A does not show a plate member and only generally shows a mobile phone 110 and external communication module 100. In the present application, the claimed plate member is a separate piece that attaches to the second housing to cover at least a portion of a display. (See, e.g., FIG. 5). Neither Haller et al., nor the other references of record, describes any sort of plate member or other piece that attaches to the second housing to cover at least a portion of the display. While a faceplate is mentioned in Haller et al., there are no further teachings as to the specifics of the faceplate. It is not apparent whether the mobile phone 110 illustrated in FIG. 6A even includes a faceplate, or whether that faceplate includes "a transparent area that exposes a display," as required by Applicant's claim 1.

Haller et al. also fails to teach or suggest a plate member printed with information to identify a programmer type. The Office Action does not present any prior art references that would have provided any teaching or suggestion to print information on a plate member. As a result, a *prima facie* case of obviousness has not been established because each and every element of Applicant's claim 1 is not taught or suggested by the references of record.

It is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness.¹ In doing so, the Examiner must determine whether the prior art provides a

¹ *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

“teaching or suggestion to one of ordinary skill in the art to make the changes that would produce” the claimed invention.² A prima facie case of obviousness is established only when this burden is met.

The Court of Appeals for the Federal Circuit recently addressed the evidentiary standard required to uphold an obviousness rejection.³ Specifically, the Federal Circuit stated: “[the] factual question of motivation is material to patentability, and (can)not be resolved on subjective belief and unknown authority.”⁴ This finding must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.⁵ Deficiencies in the evidentiary record cannot be cured by general conclusions such as “general knowledge” or “common sense.”⁶

Accordingly, the Examiner cannot rely on unsupported, conclusory statements to close holes in the evidentiary record.⁷ For example, the Examiner may not use the conclusory statement that, “it is well known and common to have printed information on a programmer” to establish Applicant’s claim 1 is obvious. Similarly, it is improper to rely on the conclusory statement, “it would have been obvious to one of ordinary skill in the art at the time of the invention to customize the faceplate by printing information identifying the type of programmer” to establish obviousness of Applicant’s claim 1. (Office Action, page 4, item 9). The Examiner provided no support, in the form of a pertinent prior art teaching, for such a conclusion.

Unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill in the art to incorporate the features of Applicant’s independent claim 1, claim 1 and dependent claims 2-17 should be allowed.

Dependent Claims 2-17

Claims 2-17 depend from independent claim 1. As established above, claim 1 is patentable over the cited references, and as a result, claims 2-17 are also patentable over the cited references. Applicant also traverses the rejections of claims 2-17. The prior art of record fails to

² *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

³ *In re Lee*, 61 USPQ2d 1430 (CAFC 2002).

⁴ *Id.* at 1434.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

teach each and every element of claims 2-17, and the rejection of claims 2-17 should be withdrawn. Applicant addresses some of the dependent claims below for purposes of illustration.

For example, nothing in the cited prior art references teaches or suggests a medical device programmer including a plate member printed with personalization information to identify a patient or a clinic, as recited by claims 2 and 3, respectively. As previously established, the Examiner cannot rely on unsupported, conclusory statements to close holes in the evidentiary record.⁸ It is improper for the Examiner to state that “it is well known and common to put [personalization information to identify a patient or clinic] on a device for easy identification, especially at a hospital or clinic” in order to assert Applicant’s claims 2 and 3 are obvious in view of Haller et al. (Office Action, page 4, item 9). Rather, the Examiner must identify a prior art teaching that would have suggested modification to provide such personalization information on a plate member, as defined in claims 2 and 3.

Similarly, it is improper to state that “printing [patient or clinic] information on the faceplate disclosed by Haller would have been obvious . . . since the faceplate is removable . . .” in order to assert Applicant’s claims 2 and 3 are obvious in view of Haller et al. (Office Action, page 4, item 9). The conclusions of obviousness by the Examiner are improper because the Examiner is not relying on prior art references to establish a teaching and motivation to modify a faceplate with such printed information. Instead, the Examiner’s conclusion of obviousness is based entirely on unsupported conjecture and the benefit of hindsight in view of Applicant’s disclosure. The rejections of claims 2 and 3 should be withdrawn.

With respect to the rejection of claims 4 and 5, which depend from claim 1, the Office Action stated, without any support, that “it would be obvious to one of ordinary skill in the art at the time of the invention to customize Haller’s faceplate using pictures and words . . .” (Office Action, page 5, item 10). Again, the prior art references of record do not teach or suggest a medical device programmer including a plate member printed with information to identify a programmer type, much less information in the form of graphics or text (as recited by claims 4 and 5, respectively). Absent some pertinent teaching in the prior art, the Examiner’s unsupported conclusion of obviousness cannot support a prima facie case of obviousness. For at least this reason, the rejections of claims 4 and 5 should be withdrawn.

⁸ *Id.*

With respect to the rejection of claim 6, the Office Action cited Haller et al., col. 21, lines 46-50, and stated that “Haller discloses that the plate member is molded to define one or more apertures to accommodate buttons extending outward from the programmer.” (Office Action, page 5, item 11). At col. 21, lines 46-50, Haller et al. only states “an off-the-shelf mobile telephone or PDA 110 may be modified such that only a limited number of buttons having predetermined functions are presented to and available for patient 5 to push.” The Office Action explained that “buttons protruding from underneath the faceplate require the faceplate to have apertures in those locations . . .” Applicant respectfully disagrees with the Examiner’s conclusion that this teaching in Haller et al. renders claim 6 obvious.

The disclosure referred to in the Office Action does not teach a programmer including a plate member defining one or more apertures to accommodate buttons extending outward from the programmer. It is not apparent from Haller et al. whether a faceplate is used to modify an off-the-shelf mobile telephone or PDA 110 or whether the faceplate would be located such that it would even require apertures for buttons. Neither Haller et al. nor any other prior art teaching would have suggested by attaching a faceplate with one or more apertures to accommodate buttons extending from a programmer.

The prior art also fails to teach each and every element of claim 7, which depends from claim 1 and recites an aperture in the second housing for accessing a software loading port, wherein the plate member is sized to cover the aperture. The Office Action cited Duncan et al. as teaching an aperture for uploading software. (Office Action, page 8, item 20). However, the Office Action does not cite any prior art that teaches or suggests an aperture in a second housing or a plate member sized to cover an aperture that provides access to a software loading port.

The cited art makes no mention of the positioning a plate member over an aperture in a housing for accessing a software loading port as recited in Applicant’s claim 7. As described in the present application, it may be advantageous for a programmer to include an aperture in a second housing member and a loading port accessible through the aperture. For example, a plurality of generic programmers having common hardware components may be pre-manufactured and stored, and when a specific type of programmer is ordered, one of the generic programmers may be loaded with the appropriate software through the exposed loading port as one of the final steps in the manufacturing process. (See paragraphs 87 and 88 at page 17). The

plate member is subsequently placed on the second housing member to cover the loading port, thereby blocking access to the loading port. The cited art does not teach or suggest each of the elements of claim 7 or a motivation for modifying a medical device programmer to arrive at the invention defined by claim 7.

Claim 9 depends from claim 1 and recites a plate member selected from a plurality of plate members having different configurations based on the configuration of the plate member and a type of programmer being assembled. Claim 10 depends from claim 9. With respect to the rejection of dependent claims 9, Applicant respectfully disagrees with the Examiner's conclusions.

First, Haller et al. does not disclose a plate member "selected from one of a plurality of plate members having different configurations based on a match between the configuration of the plate member and type of medical device programmer being assembled," as the Office Action asserted. (Office Action, page 6, item 13). As previously described, Haller et al. only states that a mobile telephone or a PDA/mobile telephone may have a removable faceplate. There is absolutely no basis in Haller or any other prior art of record that would support the Examiner's position.

Second, the Examiner provided no support for the assertion that "it is simply a matter of design choice to have different plate members to choose from or to make the plate according to the configuration of the programmer." (Office Action, page 6, item 13). The motivation to add such a feature would have come only from Applicant's own disclosure, which recognizes that the availability of a custom-printed plate member may facilitate the pre-manufacture of patient programmers. For example, as discussed in reference to claim 7 above, a plurality of generic patient programmers having common hardware components may be pre-manufactured and stored. (See paragraph 87 at page 17).

When a specific type of programmer is needed, a generic patient programmer is programmed with appropriate software functionality. Then, a plate member with appropriate indicia is attached to the housing to differentiate the programmer according to its specific programmed functionality. Neither Haller et al. nor any of the other references of record suggests this advantage, nor any other advantage, of having a plurality of plate members with different configurations that match a type of medical device programmer. Absent sufficient teachings in

the prior art, the Examiner is not permitted to dismiss the requirements of Applicant's claims as mere design choice. Rather, the law requires the Examiner to identify a pertinent teaching in the prior art.⁹ The mere fact that one skilled in the art could have provided different plate members is insufficient. Rather, there must be some motivation in the prior art (and not within Applicant's disclosure) to undertake such modifications.

With respect to the rejection of claims 14 and 15, the Office Action asserted that because Haller et al. does not disclose any direct connection between the display and the telemetry module, the display and telemetry circuitry are not on the same circuit board. (Office Action, page 7, item 16). Applicant respectfully disagrees with the Examiner's interpretation of Haller et al.. The Examiner relied on an improper finding of an inherent disclosure in Haller et al. The fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); MPEP 2112. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112. No reasonable support has been provided for the determination that the programmer in Haller et al. necessarily includes two circuit boards, as recited by claim 14, much less display and telemetry circuitry on separate circuit boards, as recited by claim 15.

As the Examiner recognized, even assuming Haller et al. teaches two separate circuit boards, Haller et al. fails to teach first and second circuit boards enclosed within first and second housing members, as required by Applicant's claim 14. (Office Action, page 7, item 16). Applicant respectfully disagrees with the Examiner to the extent the Examiner contends it would have been obvious to incorporate the communications module 100 of Haller et al. (which includes the telemetry module) into a PDA-type programmer. Furthermore, merely combining the communications module 100 of Haller et al. into a PDA-type programmer does not necessarily mean the PDA programmer would include two circuit boards. There is no motivation in Haller et al. for modifying a programmer to include first and second circuit boards enclosed within first and second housing members.

⁹ *In re Lee*, 61 USPQ2d 1430 (CAFC 2002).

The present application recognizes advantages to including two circuit boards within first and second programmer housing members. For example, as recited in claim 15, it may be desirable to mount telemetry and display circuitry on separate circuit boards. Separate circuit boards may allow control circuitry to selectively disable display electronics connected to a first circuit board during telemetry sessions administered by components on a second circuit board, thereby possibly reducing interference caused by noise associated with the display. (See paragraph 107 at page 21).

Claim 16 specifies that the second circuit board includes control circuitry to drive the telemetry circuitry and display circuitry. In rejecting claim 16, the Office Action found that because “display/user 108 [of Haller et al.] is . . . capable of sharing its circuit board with the microprocessor . . .,” Haller et al. discloses control circuitry to drive the telemetry and display circuitry. (Office Action, page 8, item 17). The Applicant traverses because, again, the fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); MPEP 2112. The fact that Haller et al. is capable of including the limitations of dependent claim 16 is not itself a sufficient showing to render claim 16 obvious. The Examiner has not provided any other prior art references that teach or suggest the limitations of claim 16.

In view of the fundamental shortcomings of the cited art identified above with respect to independent claim 1, Applicant reserves comment concerning the additional limitations expressed in the dependent claims not specifically traversed and does not acquiesce in the Examiner’s application of the teachings of Haller et al., Lin et al., Duncan et al., and Stroebel et al., to those claims.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant’s claims 1-17 under 35 U.S.C. 103(a). Withdrawal of these rejections is requested.

CONCLUSION

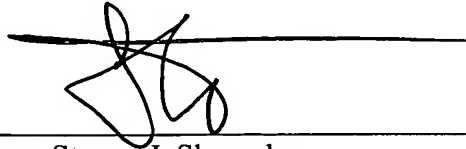
Claims 1-17 in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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7-12-06

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